

REMARKS

Telephonic interview

Applicants thank the Examiner for agreeing to the telephonic interview, which was conducted on April 2, 2009. As per the Examiner's suggestion, a formal response to the Office Action is being submitted herewith.

Claims

Claims 1–5 and 9–16 are currently under examination. Claims 6–8, which are directed to non-elected subject matter, were previously cancelled. Claims 17 and 18 are hereby cancelled without prejudice or disclaimer.

Amendments

Amended claim 1 recites the subject matter of the previously examined claim 17, which is hereby cancelled without prejudice or disclaimer. Support for the amendment of claim 1 can be found in, for example, page 2, lines 1-8; the paragraph bridging pages 4 and 5; and page 5, paragraphs 1-3 of the originally-filed specification.

It is respectfully submitted that the claim amendments do not raise new matter. Furthermore, Applicants' amendment of the claims complies with the requirements set forth under 37 CFR §1.116 and that the amendments presented herein do not impose additional search burden. Entry thereof is respectfully requested.

Rejections under 35 U.S.C. §102/§103

The contention that Gundling's disclosure (US patent application publication no. 2002/0068821; published: June 6, 2002; *hereinafter* the '821 publication) anticipates claims 1–3 of the present application has been sustained.

The rejection of claim 4 under §103(a) as allegedly rendered obvious by the aforementioned Gundling et al. in view of Madden (US patent application publication No. 2005/0054847) has been sustained. Additionally, the rejection of claim 5 under §103(a) as allegedly rendered obvious by Gundling et al. in view of Kilaas' disclosure in WO

04/003231 has been sustained.

Applicants' disagree with the PTO's assessment that the disclosure in the above-cited references anticipates or *prima facie* renders obvious the claims of the instant application. However, it is respectfully submitted that these rejections are rendered moot by the aforementioned amendments. Namely, claim 17 was not rejected under these sections, and amended independent claim 1 recites the subject matter of this claim. Withdrawal of the rejections is respectfully requested.

Claim interpretation

The Office Action at page 9 alleges that the claim term selectively isolated is "extremely broad and it cannot be determine [sic] how the limitation defines or distinguishes the claim over the prior art." This contention and the art rejection based thereon are both respectively traversed. At the outset, Applicants have amended the claim term to recite "specific" isolation. *Ipsis verbis* support for the claim language can be found in, for example, page 2, lines 1-8; the paragraph bridging pages 4 and 5; and page 5, paragraphs 1-3 of the originally-filed specification. The Examiner is also cordially requested to review the disclosure contained in the Examples, for example, Example 3 at page 10 of the originally-filed specification. Applicants thus aver that the instant specification provides explicit guidance as to "specific isolation of RNA" as recited in the claims. Moreover, in view of the recognized physiochemical differences between the two molecules in question (for example, stranded-ness, melting temperature, base composition, etc.), any skilled worker can reasonably ascertain the specificity of the isolation process. Explicit description thereof is not necessary at all. In any event, in order to purely facilitate prosecution, the claims have been amended to recite the specificity of isolation of RNA relative to DNA.

New rejection under §103(a)

Claims 1-5 and 9-18 are rejected under §103(a) as allegedly unpatentable over the aforementioned Gundling et al. (the '821 publication) in view of Belly (USP 7,267,950;

hereinafter the '950 patent) further in view of Goudsmit (US patent application publication 2001/0021518; *hereinafter* the '518 publication). This contention is respectfully traversed.

At page 10, the Office Action contends that:

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Regarding claim 1, 10, 12, 17 and 18, Gundling et al teach a method the isolation of RNA from samples comprising a mixture of nucleic acids wherein the method comprises providing a magnetite solid phase; providing a binding buffer which comprises guanidinium thiocyanate at a concentration of greater than 3 mol/l (entire patent and 0022), mixing the sample with the magnetite solid phase and the binding buffer, where a phosphate concentration which supports the binding of RNA is present in the mixture, isolation of the solid phase with the bound RNA and further eluting the RNA from the solid phase (Example 1 and 2). Gundling further teaches wherein the binding buffer may comprise sodium phosphate based on the investigator's desired pH of the buffer solution (0013).

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Applicants submit that the entirety of the disclosure in the '821 publication fails to impart any teaching or suggestion of specific isolation of RNA, as recited in the claims. While Gundling may disclose a generic method for the isolation of RNA, there is no mention of DNA and how the method is geared towards *specific* isolation of one over the other.

Belly deals with the isolation of RNA for use in intraoperative diagnostic applications. The reference discloses the use of commercial RNA isolation kits and further discloses the use of PCR in the analytical step. See, col. 3, lines 45–65 and the Examples of the '950 patent. There is no mention of a magnetite solid phase. Additionally, as conceded by the Examiner at page 11 of the Office Action, “Gundling in view of Belly do not expressly teach wherein the binding buffer comprises a chelator, such as EDTA, in a concentration between 5 and 200 mM.”

Goudsmit teaches a method for the isolation of single stranded nucleic acid material from double stranded nucleic acid material. mRNA is disclosed as a type of single stranded nucleic acid material. The '518 publication teaches that the use of a "silicium-based solid phase" allows separation because "ss-nucleic acid did not bind to silica particles or diatomeous earth in the presence of buffer L11." See, section [0010] of the '518 publication. The cited reference is completely silent with regard to the magnetite solid phase and use thereof in specific isolation of RNA molecules, as recited in the present claims. As such, a combination of the cited references fails to *prima facie* render obvious the claims of the present application. Obviousness requires a suggestion of all the elements in a claim (*CFMT Inc., v Yieldup Int'l Corp.* 349 F.3d 1333, 1342 [68 USPQ2d 1940] (Fed. Cir. 2003)) and requires a reason that would have prompted [a skilled worker] to combine the elements in the way the claimed new invention does. *Ex parte Alexander* (Decided November 30, 2007; 86 USPQ2d 1120). Withdrawal of the rejection is respectfully requested.

Furthermore, Goudsmit teaches away from the subject matter of the instant invention. For example, in section [007] of the '518 publication, Goudsmit expressly teaches that the method comprises employing "a liquid comprising a chaotropic agent and a nucleic acid binding solid phase, whereby the liquid has a composition such that double stranded nucleic acid binds to the solid phase and a substantial amount of single stranded nucleic acid does not and separating the solid phase from the liquid (emphasis added)." Thus, Goudsmit teaches the separation of a solid phase comprising double stranded nucleic acid (i.e., DNA) and not RNA. Moreover in section [0011], Goudsmit further teaches that "The solid phase to be used is less critical. Important is that it should bind nucleic acids reversibly (emphasis added)." As such, a Goudsmit in combination with the aforementioned Gundling and Belly fails to render obvious the instant claims. It is improper to combine references where the references teach away from their combination. See, MPEP §2145 and *In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983).

Withdrawal of the rejection is respectfully requested.

Applicants bring to the Examiner's attention WO

In view of the above remarks, favorable reconsideration is courteously requested. If there are any remaining issues which could be expedited by a telephone conference, the Examiner is courteously invited to telephone counsel at the number indicated below.

The Commissioner is hereby authorized to charge any fees associated with this response to Deposit Account No. 13-3402.

Respectfully submitted,

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